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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,790	06/06/2001	John E. Sims	2008-US	9011
22932	7590	12/04/2003	EXAMINER	
IMMUNEX CORPORATION LAW DEPARTMENT 51 UNIVERSITY STREET SEATTLE, WA 98101			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/876,790	SIMS ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 6, 7, 9, 10, 12, 13 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 7, 10, 13, 25, 28, 31 and 34 is/are allowed.
- 6) ☒ Claim(s) 1, 6, 9, 12, 24, 26, 27, 29, 30, 32, 33, 35 is/are rejected.
- 7) ☒ Claim(s) 29, 32, 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6/19/03</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Receipt of Applicants' arguments and amendment, filed on 21 August 2003, is acknowledged. Claims 1, 2, 9-10 have been amended. Claims 3-5, 8, 11 and 14-23 have been cancelled, and new claims 24-35 have been added. Thus claims 1-2, 6-7, 9-10, 13 and 24-35 are pending and under consideration.

2. The following previous objection is withdrawn in light of Applicants amendments filed on 08/21/03:

(I) The objection to the title is withdrawn.

(II) The objection to claims 1 and 2, for reciting non-elected SEQ ID Nos is withdrawn.

(III) The rejection of claims 9-10 made under 35 U.S.C. 101, for not reciting "an isolated host cell", is withdrawn.

(IV) The rejection of claims 1, 2, 6, 7, 9, 10, 12 and 13 made under 35 U.S.C § 102(e) as being anticipated by Yang Pan (U.S. Patent 6,117,654), is withdrawn.

(V) The rejection of claims 1, 2, 6, 7, 9-10, 12 and 13, under 35 U.S.C § 112, first paragraph, as not providing an enabling disclosure is withdrawn.

#### ***Information Disclosure Statement:***

3a. United States Patent 6,227,654, cited on the PTO-1449 form submitted by Applicants on 19 June 2003 has not been considered, because the relevance of this patent to the instant invention is not clear. The invention of U.S. patent, 6,227,654 is drawn to an ink jet printing mechanism.

#### ***Response to Applicants' Arguments and Amendment:***

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***Election/Restrictions:***

4. Applicants request that restriction requirement between polynucleotide sequences encoding SEQ ID Nos: 3, 8, 9 and 10 be reconsidered, since the polypeptides of SEQ ID Nos:8, 9 and 10 are encoded by splice variants of SEQ ID NO:1, and are therefore, splice variants of IL-1 Zeta. Applicants argue that at worst that the nucleotide sequences encoding these polypeptides should be considered species within the genus of IL-1 zeta.

Applicants' arguments have been fully considered but are not deemed persuasive, because the nucleotide sequences encoding SDEQ ID Nos:8, 9 and 10 are structurally different and are not obvious over the nucleotide sequence of SEQ ID NO:1. Although the nucleotide sequences encoding SEQ ID NOs:8, 9 and 10 may share some homology at certain domains to SEQ ID NO:1, the overall homology between SEQ ID NO:5, 6 (which encode SEQ ID NO:8, 9, respectively) to SEQ ID NO:1 is only 88%, while the overall homology between SEQ ID NO:8, 9 and SEQ ID NO:3, is only 89%. It is well known in the prior art that changes in a nucleotide sequence can have a dramatic affect on the protein product encoded by the sequence, therefore, two nucleotide sequences that share 88% homology would not be expected to encode the same polypeptide.

The restriction requirement between SEQ ID Nos:1, 5, 6 and 7 is still deemed proper and is therefore made FINAL.

Applicants' reservation of the right to pursue claims to the non-elected SEQ ID Nos in divisional applications is acknowledged.

***New rejections necessitated by Applicants amendment:***

**Claim Rejections - 35 U.S.C. § 101:**

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6a. Claims 26, 29, 32 and 35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 26 recites "a polynucleotide encoding .....", which encompasses the polynucleotide, as it occurs in nature. However, since Applicants do not intend to claim a naturally occurring products amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claim 26 be amended to recite "an isolated polynucleotide.....", Appropriate correction is required.

Claims 29, 32 and 35 are also rejected under 35 U.S.C. 112, first paragraph, so long as they depend from claim 26 for the limitations set forth directly above.

**Claim Rejections - 35 U.S.C. § 112:**

7a. Claims 1, 6, 9, 12, 24, 27, 30, 33, while being enabling for the isolated nucleic acid comprising the nucleotide sequence recited in instant claim 2, does not reasonably provide enablement for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:3, wherein the polypeptide has one or more changes in amino acid sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claim 24 recites "one or more changes in amino acid sequence", however, it is well known in the prior art that changes in amino acid sequence can have a dramatic affect on the functional integrity of the protein. A skilled artisan would expect that the variation in the amino acid sequence would at best impaired the function of the protein and at worst result a nonfunctional or an entirely different product from that of the claimed invention. Therefore, it would be impossible to predict with certainty the effect of a substitution, insertion, or deletion of a series of amino acid residues or even one amino acid, on the functional integrity of the protein . In order to make an accurate assessment of the modifications encompassed by these claims and to determine the function of the protein would require undue experimentation.

Therefore, one of ordinary skill in the art would not know how to make or use all of the polynucleotides encoding polypeptides having one or more changes in amino acid sequence of SEQ ID NO:3, as encompassed by claim 24.

With respect to claim 1 which recites "capable of hybridizing . . . ." The specification is non-enabling for an isolated polynucleotide that does not hybridize to the polynucleotide of SEQ ID NO:1 and is only capable of hybridizing, if further modified, since Applicants have not taught how to further modify the polynucleotide such that it can hybridize the polynucleotide of SEQ ID NO:1. It has been held that an element is "capable of" performing a function is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claims 6, 9, 12, 27, 30 and 33 are also rejected under 35 U.S.C. 112, first paragraph, so long as they depend from claims 1 and 24 for the limitations set forth directly above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 6, 9, 12, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8a. Regarding claim 1, the phrase "include" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is suggested that Applicant recite "requires" instead of "includes".

Claims 6, 9, 12, are also rejected under 35 U.S.C. 112, second paragraph, so long as they depend from claim 1 for the limitations set forth directly above.

**Conclusion:**

9a. Claims 2, 7, 10, 13, 25, 28, 31, 34 are allowable.

9b. Claims 1, 6, 9 and 12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
26 November 2003

  
GARY KUNZ  
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